

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NOVARTIS PHARMACEUTICALS	)	
CORPORATION, NOVARTIS AG,	)	
NOVARTIS PHARMA AG, NOVARTIS	)	
INTERNATIONAL PHARMACEUTICAL	)	
LTD. and LTS LOHMANN THERAPIE-	)	
SYSTEME AG,	)	
	)	
Plaintiffs,	)	C. A. No. 13-00527-RGA
v.	)	
	)	
NOVEN PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

**NOVEN PHARMACEUTICALS, INC.'S  
ANSWER TO PLAINTIFFS' COMPLAINT**

Defendant Noven Pharmaceuticals, Inc. ("Noven Pharma"), through its undersigned counsel, hereby answers the Complaint of plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd., and LTS Lohmann Therapie-Systeme AG (collectively, "Plaintiffs") as follows. This Answer is based on Noven Pharma's knowledge as to its own activities, and upon information and belief as to the activities of others. The numbered paragraphs below correspond to the numbered paragraphs in the Complaint.

**NATURE OF ACTION**

1. Admitted that Plaintiffs purport to state claims for patent infringement.

Otherwise denied.

**PARTIES**

2. Noven Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

3. Noven Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

4. Noven Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

5. Noven Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

6. Noven Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

7. Admitted.

8. Because Noven Therapeutics, LLC ("Noven Therapeutics") has been dismissed from this case, no response is required. To the extent a response is required, admitted that Noven Therapeutics is a limited liability company organized and existing under the laws of the State of Delaware, and has a place of business at 11960 SW 144th Street, Miami, Florida 33186. Otherwise denied.

9. Because Hisamitsu Pharmaceutical Co., Inc. ("Hisamitsu") has been dismissed from this case, no response is required. To the extent a response is required, admitted.

10. Admitted that Noven Therapeutics is a wholly-owned and independent subsidiary of Noven Pharma, and that Noven Pharma is an indirect wholly-owned subsidiary of Hisamitsu.

11. Denied.

12. This paragraph states a description of how the named defendants will be referred to collectively in the Complaint, to which no response is required. To the extent a response is required, denied that the defendants are all properly referred to as “Noven.”

**JURISDICTION AND VENUE**

13. This paragraph states legal conclusions to which no response is required. To the extent a response is required, admitted that Plaintiffs purport to state claims of patent infringement that arise under the patent laws of the United States of America, and that Plaintiffs purport to state claims such that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Otherwise denied.

14. Admitted that Noven Pharma is incorporated in Delaware. Because Noven Therapeutics has been dismissed from this case, no response is required as to this entity. To the extent a response is required, denied that Noven Therapeutics is incorporated, but admitted that Noven Therapeutics is a Delaware limited liability company. The remaining allegations in this paragraph state legal conclusions to which no response is required. To the extent a response to the remaining allegations is required, denied.

15. Because Hisamitsu and Noven Therapeutics have been dismissed from this case, no response is required as to these entities. Noven Pharma admits that it is in the business of researching, developing, manufacturing, marketing, distributing, and selling certain pharmaceuticals products in the United States, including Delaware. Noven Pharma does not contest that this Court has personal jurisdiction over Noven Pharma for purposes of this action only. The remaining allegations in this paragraph are denied.

16. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied. Noven Pharma states, however, that it will not contest personal jurisdiction in this judicial district for purposes of this case.

17. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied. Noven Pharma states, however, that it will not contest venue in this judicial district for purposes of this case.

**CLAIM FOR RELIEF – PATENT INFRINGEMENT**

18. Admitted that Novartis Pharmaceuticals Corp. (“NPC”) is the holder of approved drug application (“NDA”) No. 22-083 for Exelon® Patch (rivastigmine transdermal system), 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 dosage strengths, which is indicated for the treatment of mild to moderate dementia of the Alzheimer’s type and mild to moderate dementia associated with Parkinson’s disease. Admitted that the United States Food and Drug Administration approved the 4.6mg/24 hr and 9.5 mg/24 hr dosage strengths on July 6, 2007, and the 13.3 mg/24 hr dosage strength on August 31, 2012. Noven Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegation that NPC sells in the United States Exelon® Patch (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3mg/24 hr dosage strengths), and therefore denies the same. Otherwise denied.

19. Admitted.

20. Admitted that Novartis AG (“NAG”) is listed on the face of U.S. Pat. No. 6,316,023 (“the ’023 patent”) as an assignee, and that the ’023 patent states on its face that it issued on November 13, 2001. Denied that the ’023 patent was duly and legally issued. Noven Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations stated in this paragraph, and therefore denies the same.

21. Admitted that Exhibit A attached to the Complaint appears to be a copy of the '023 patent. The remaining allegations stated in this paragraph set forth legal conclusions to which no response is required. To the extent a response is required, denied.

22. Admitted that NAG is listed on the face of U.S. Pat. No. 6,335,031 ("the '031 patent") as an assignee, and that the '031 patent states on its face that it issued on January 1, 2002. Denied that the '031 patent was duly and legally issued. Noven Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations stated in this paragraph, and therefore denies the same.

23. Admitted that Exhibit B attached to the Complaint appears to be a copy of the '031 patent. The remaining allegations stated in this paragraph set forth legal conclusions to which no response is required. To the extent a response is required, denied.

24. Admitted that NAG and LTS Lohmann Therapie-Systeme GmbH are identified on the face of the '023 patent as the assignees of that patent, and that NAG and LTS Lohmann Therapie-Systeme GmbH Co. KG are identified on the face of the '031 patent as the assignees of that patent. Noven Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations stated in this paragraph, and therefore denies the same.

25. Admitted with respect to Noven Pharma. Denied with respect to Hisamitsu and Noven Therapeutics.

26. Admitted with respect to Noven Pharma. Denied with respect to Hisamitsu and Noven Therapeutics.

27. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, denied.

28. This paragraph states a legal conclusion to which no response is required. To the extent a response is required, admitted that Noven Pharma was aware, at the time it filed its ANDA, of the '023 and '031 patents. Otherwise denied.

29. Denied.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. The allegations stated in this paragraph set forth legal conclusions to which no response is required. To the extent a response is required, denied.

#### **PRAYER FOR RELIEF**

Noven Pharma denies that Plaintiffs are entitled to the relief requested in the Complaint or to any relief whatsoever.

#### **AFFIRMATIVE DEFENSES**

##### **First Affirmative Defense**

Noven Pharma has not infringed, does not infringe, and will not infringe any valid claim of the '023 patent or the '031 patent.

##### **Second Affirmative Defense**

The claims of the '023 patent and the '031 patent are invalid for failure to comply with one or more sections of Title 35 of the United States Code, including sections 102, 103, and 112.

##### **Third Affirmative Defense**

Plaintiffs have failed to state a claim upon which relief may be granted.

Dated: April 23, 2013

PHILLIPS, GOLDMAN & SPENCE, P.A.

/s/ John C. Phillips, Jr.

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